PHARMACEUTICAL DISTRIBUTORS ASSOCIATION

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April 5, 2002

VIA COURIER

Donald S. Clark
Office of the Secretary
Federal Trade Commission
Room H-172
600 Pennsylvania Ave., NW
Washington, DC 20580

RE: Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy Public Hearings, Spring and Summer, 2002

Dear Secretary Clark:

The Pharmaceutical Distributors Association ("PDA") is a trade association of companies that are wholesalers of prescription and nonprescription drugs. These companies buy drugs directly from manufacturers, from full line wholesalers who are "authorized" distributors for manufacturers and from wholesalers who are not "authorized" distributors of all the drugs that they sell. PDA members in turn resell these drugs to other wholesale distributors, to retail pharmacies, to health care entities and to physicians.

PDA member companies are sometimes called "secondary" wholesalers because they do not carry a full line of pharmaceuticals such as the major wholesalers like McKesson, AmerisourceBergen and Cardinal Health. By far the largest volume of secondary wholesale transactions involves the acquisition of pharmaceuticals from manufacturers before they increase the prices for their products. Like full line wholesalers, PDA members are licensed by each state in which they are authorized to do business and the facilities of PDA member are subject to inspection by the FDA, DEA and other state and federal authorities. PDA members are subject to the same regulations and restrictions as full line distributors.

The PDA welcomes this opportunity to comment on what we believe is the inappropriate use of the intellectual property laws to restrain or otherwise inhibit legitimate competition in vibrant downstream markets. While much of the focus of the

FTC's Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy Public Hearings has been on the intersection of patent and antitrust law and how to reconcile what at times appear to be competing objectives, we believe that the aggressive use of trademark litigation against lawful resellers of products warrants closer study by the FTC and this series of public hearings. While the PDA supports the protection and enforcement of legitimate intellectual rights, copyright and trademark litigation should not be used as a tool to enforce vertical restraints and inhibit competition in secondary markets. "Protectionism should not be concealed behind a convenient interpretation of trademark laws." NANCY T. GALLINI AND AIDAN HOLLIS, A CONTRACTUAL APPROACH TO THE GRAY MARKET, 19 Int'l Rev. of Law and Economics 20 (1999). Instead, "[t]he goal of patent law and copyright law, as enunciated in Article I section 8 of the Constitution is 'To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Timothy J. Muris, Chairman, Federal Trade Commission, Address at the ABA Association Antitrust Section Fall Forum (November 15, 2001) (transcript available at http://www.ftc.gov/speeches/muris.intellectual.htm).

This paper describes the secondary distribution industry, how it benefits consumers and various ways that manufacturers and their designated distributors have use the intellectual property laws to interfere with secondary distributors and their customers.

Secondary Distributors

The secondary distribution industry, sometimes pejoratively called the "diversion" industry, is a product of the various types of pricing schemes used by American manufacturers and their primary distributors. It is standard practice for manufacturers and even distributors to offer different net prices to different customers. These variations, which can range from different wholesale prices, terms of sale, incentives, rebates or other allowances, are often quite substantial. Because manufacturers and distributors choose to price discriminate among different customers – a right that they have so long as they comply with the requirements of the Robinson-Patman Act[1] – manufacturers set into place the market conditions that cause goods to move from regions or customers that can purchase at the lower prices to regions and customers that face higher prices. PDA members purchase such goods, which can range from high-end pharmaceuticals to everyday products such as shampoo and toothpaste, at lower prices and resell them – often at substantial savings – to retailers and end-users.

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[1] 15 U.S.C. § 13(b).

PDA members buy and sell first quality, legitimate branded goods. Neither the PDA nor its members condone the trade in counterfeit or "knock-off" goods. Such goods violate U.S. and international intellectual property laws, can dilute the value of manufacturers' trade and service marks and can confuse or mislead consumers. Instead, PDA members respond to market conditions by purchasing branded goods at lower prices and reselling them. PDA members do not knowingly buy or sell counterfeit goods.

There are two primary ways in which secondary distributors serve their customers. Secondary distributors take advantage of geographic pricing differentials – where manufacturers price the identical product at different prices in different countries or regions of the United States – by buying products in lower priced regions or countries and reselling them in higher priced regions. Secondary distributors also take advantage of temporal price differentials by purchasing goods in bulk prior to manufacturer-announced price increases or during special promotional periods and reselling the goods when the price increase takes effect or the promotional pricing ceases. In either instance, secondary distributors purchase first quality, identical goods and resell them at substantial savings, resulting in benefits along the supply chain and savings for consumers. In short, secondary distributor purchases and sales represent the free market at work.

Because secondary distributors compete against primary distributors and indeed manufacturers themselves, manufacturers and primary distributors have gone to considerable efforts to interfere with the free flow of goods among secondary distributors and their customers. Manufacturers and their distributor partners have collectively, under the guise of concerted political activity permitted by the Noerr-Pennington doctrine,[2] accused secondary distributors of various forms of nefarious conduct including trafficking in counterfeit goods, buying and selling damaged goods that could impact the safety and welfare of consumers and even dealing in stolen goods. While such concerted conduct may itself be worthy of an FTC investigation, it is both beyond the scope of these hearings and the PDA's comments.

When manufacturers successfully exploit the intellectual property laws to exclude secondary distributors, it is competition and the American consumer that lose out. The secondary market provides consumers the opportunity to purchase first quality branded products at discount prices. Indeed, without the secondary market for first-quality goods, many discount retailers and warehouse clubs would find it difficult to offer consumers the quality goods and low prices that they currently enjoy.

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[2] *Eastern Railroad & Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers of America v. Pennington*, 361 U.S. 657 (1965).

The First Sale Doctrine

There is a long history of manufacturers attempting to use the intellectual property laws to control resale prices, competition in and other aspects of the secondary markets. The trademark and copyright laws provide manufacturers with an avenue to attempt to accomplish what they would otherwise control through direct restraints such as minimum resale prices on their goods. However, an agreement requiring the distributor to adhere to specific prices or agree to a minimum resale price would be a *per se* violation of Section 1 of the Sherman Act. *See, e.g. Business Electronic Corp. v. Sharp Electronic Corp.*, 485 U.S. 717, 735-36 (1988), *Arizona v. Maricopa County Med. Society*, 457 U.S. 332, 346-48 (1982). Once a manufacturer sells its product to a distributor or retailer, it may not deprive consumers of the benefit of competition in the subsequent traffic. *Dr. Miles Medical Co. v. John D. Park & Sons Co.*, 220 U.S. 373, 409 (1911). Thus, manufacturers have resorted to copyright and trademark arguments.

As early as the beginning of the 20th Century, manufacturers have tried to use trademark law to control subsequent resale pricing and other distribution practices. In the landmark case of *Bobbs-Merrill Co. v. Straus*, 210 U.S. 339 (1908), a book publisher inserted a notice in its books that any retail sale at a price less than one dollar would constitute an infringement of its copyright. *Id.* at 341 Retail giant Macy's ignored the publisher's notice and sold the books for less than one dollar, thus violating the copyright holder's terms for reselling its books. The U.S. Supreme Court rejected the publisher's attempt to use the copyright laws to restrain competition in the downstream market, holding that the exclusive statutory right to vend a copyrighted work only applied to the first sale. *Id.* at 350-51. It is from *Bobbs-Merrill* that the first sale doctrine – which provides that the owner of a lawfully made copy of a copyrighted work may resell or otherwise dispose of the copy without the consent of the copyright holder – emanated.[3] The first sale doctrine sensibly balances the right of the copyright holder to enjoy the benefits of his copyright by controlling the first sale of the copyrighted work without restraining competition in the sale of the copyrighted work in downstream markets.

Despite subsequent attempts to weaken or carve exceptions in the first sale doctrine, it remains an important right for purchasers of lawful copies of copyrighted works. However, as one commentator has noted, "[t]he content of case law is mixed with regard to the promotion of price discrimination. Some provisions facilitate discrimination and others impede it. Similarly, the history of copyright legislation records a recurring contest between publishers and users over elements of the law that impinge on discriminatory marketing practices." MICHAEL J. MEURER, COPYRIGHT LAW

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[3] The first sale doctrine is now codified at 17 U.S.C. 109(a).

AND PRICE DISCRIMINATION 19 (Boston Univ. School of Law Working Paper Series, Law and Economics Working Paper No. 01-06, 2001). In recent years, manufacturers and their designated distributors attempted to carve out a new exception to the first sale doctrine, one that would have had terrible consequences for discount retailers, warehouse clubs and their millions of consumers.

Parallel Importers

As discussed in the introduction, many manufacturers choose to price discriminate among domestic distributors (on a regional basis) and international distributors (on a country by country basis) of the same product, leading to the frequent situation in which a U.S.-manufactured good is available for a lower price overseas or in a region of the United States than it is generally in the United States.[4] The manufacturer has made the profit-maximizing decision to charge certain U.S. distributors – and ultimately certain U.S. consumers – a higher price. While market forces may encourage manufacturers to engage in this type of price discrimination, equally strong market forces provide an incentive for secondary distributors to purchase these first-quality goods intended for sale in overseas or regional markets and bring them back to be sold in any region of the United States where prices are higher. For years, manufacturers had tried various intellectual property theories, including copyright and trademark infringement, to prevent the secondary market from competing with their attempts to impose and enforce artificially high prices in their distribution chain.

Fortunately for United States consumers, the United States Supreme Court recently acknowledged the propriety of parallel importation – or the importation of goods into the United States that had originally been exported for sale in a foreign market – under U.S. copyright and trademark law. *Quality King Distributors, Inc. v. L'Anza Research International, Inc.*, 523 U.S. 135 (1998) involved a United States manufacturer (L'Anza Research) that sold its shampoo products in both the United States and overseas. L'Anza Research's domestic prices were much higher than those it charged foreign distributors. One of L'Anza Research's foreign distributors sold L'Anza Research products to a United States distributor ("Quality King"), who imported the products back into the United States and sold them to retailers at discounted prices.

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[4] The Prescription Drug Marketing Act prohibits the reimportation of exported prescription drugs except by the exporting manufacturer. 21 U.S.C. Sec. 381(d)(1). No such restrictions apply to nonprescription drugs or to health and beauty aids. Accordingly, to the extent that this section discusses reimportation as opposed to domestic secondary distribution, it does not apply to prescription drugs.

L'Anza Research alleged that Quality King violated L'Anza Research's copyright in that the L'Anza Research products were affixed with a copyrighted label. Prior to *L'Anza*, several other manufacturers had enjoyed varying degrees of success with this theory that the manufacturer's intellectual property rights in the product's label trumped a legitimate owner's right to resell the product irrespective of any underlying copyright. Quality King countered, and ultimately prevailed on its theory that the first sale doctrine protected it and its supplier from L'Anza Research's copyright infringement claims.

Geographic price discrimination harms many American consumers, and the *L'Anza* decision helps reimporters and other secondary distributors mitigate the harm by removing copyright law as an impediment for importing identical nonprescription U.S. goods from foreign distributors and for free market distribution of all goods among regions of the United States.

Absent the very limited circumstances where U.S. law bars reimportation of prescription drugs, and are thus able to engage in unchecked export price discrimination at the expense of American consumers, the free market is alive and well in the United States. While free-market pharmaceutical manufacturers should be free to price their products how they see fit, they should not be permitted to use intellectual property law to prevent or obstruct the market from responding to their pricing decisions.

The industry will no doubt argue – as it consistently has in the past – that reimportation of nonprescription drugs and diversion generally should be prohibited because of questions of safety and efficacy of the reimported or diverted goods. This argument is specious – PDA members buy and sell first quality goods and are subject to the same regulations as their higher-priced distributors. However, this is beyond the scope of the PDA's paper, which deals with intellectual property law and the jurisdiction of the Federal Trade Commission. The PDA's position is that intellectual property laws – particularly trademark and copyright laws – should not be used to enforce the manufacturers' vertical restraints. Questions of safety and efficacy are best left to the purview of the Food and Drug Administration, the Agency charged with protecting the integrity of the drug, food and cosmetic supply. The first sale doctrine should control such subsequent sales, permitting the downstream markets to function and provide meaningful competition, resulting in lower prices and greater choices for U.S. consumers.

Domestic Diversion

While parallel importation of nonprescription drugs and other health and beauty aids plays an important role in providing U.S. consumers with first quality branded goods at lower prices, domestic resale plays perhaps a larger role in insuring competitive

downstream markets. Domestic diversion is nothing more than buying first quality branded goods within the United States at lower prices – due either to geographic or temporal price differentials – and reselling them in regions where – or during periods when – the prices are higher. Much in the way parallel importation helps prevent U.S. consumers from having to subsidize foreign sales and consumers, domestic diversion helps prevent one region or class of U.S. consumers from having to subsidize other sales.[5]

Lanham Act Litigation

The Lanham Act, 15 U.S.C. § 1051, *et seq.*, was introduced by Texas Congressman Fritz Lanham in 1945 and signed into law in 1946. Although the Lanham Act has been subsequently amended and modified, its core objective, to protect trade and service marks and prevent consumer confusion, remains intact. The Lanham Act has become a favorite tool of manufacturers and designated distributors to interfere with the downstream secondary distribution market in ways that Congressman Lanham could not have anticipated.

When one thinks of Lanham Act litigation, one thinks of companies or individuals misappropriating a registered trademark, diluting the value of the mark and creating confusion in the marketplace. The use of the Lanham Act to prevent such misappropriation is both consistent with its original intent and serves a procompetitive function – preserving the incentive to create valuable marks. PDA members do not misappropriate trademarks – they sell legitimate, first quality goods.

In recent years, manufacturers have put various types of product identification codes on product labels. These codes often contain detailed information about the product's place of manufacture and the manufacturer's intended route of distribution. They mean nothing to the consumer and in fact are often not perceptible to the average consumer. They should not be confused with batch codes, which contain production run information that can be used for product recalls.

Although manufacturers claim that product identification codes are affixed to products in order to facilitate product recalls, the real purpose of the product identification codes is to protect manufacturers and their designated distributors and resellers from the competition provided by the secondary market. Manufacturers will often send investigators into the field to locate products being sold at retail outlets outside

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[5] Moreover, as opposed to invoking the Robinson-Patman Act and its questionable economic underpinnings, domestic diversion provides an economically rational and efficient way to deal with price discrimination by allowing markets rather than courts to address its effects.

of the designated distribution chain. By using the product identification codes, manufacturers are often able to trace the product back to the last "authorized" distributor and then discipline or even cut off the distributor from deviating from the manufacturer's pricing and distribution instructions. This in turn deprives consumers of competitively priced products.

In order to avoid retaliation from the manufacturers and their designated distributors, some secondary distributors and their suppliers remove the product identification codes. Removing the product identification code does nothing to alter or impair the appearance of trademark affixed to the product and does nothing to change the contents of the container. Moreover, since the product information code, which is often imperceptible to consumers, does not contain any information that a consumer would be able to understand or use, the absence of such a code does not create any consumer confusion. While removing the code adds an additional expense for secondary distributors, the aggressive tactics of manufacturers and their designated distributors often force secondary distributors to incur this expense in order to avoid retribution from interests devoted to protecting their markets from competition.

While manufacturers maintain that the product identification codes are affixed only to help with recalls and maintain quality control, the true purpose of these codes was made very clear in the late 1990s when many industry interests championed proposed legislation that would have made it a *criminal* offense to remove, deface or otherwise alter product identification codes.[6]

The manufacturers and their designated distributors made this purpose very clear in the late 1990s while engaged in an aggressive lobbying campaign designed to have Congress criminalize the removal of product identification codes. Championed under the guise of consumer protection, the true motivation of the legislation's backers was to help eliminate secondary competition.[7] Indeed, according to the Beauty and Barber Supply Institute (BBSI), "[t]he bill would have a dramatic impact on the practice of unauthorized diversion of professional salon products in that many well known redistributors or diverters are know [sic] to deface and decode products to protect their sources." BBSI Executive Director Michael Spano remarks at the August 1999 National-Interstate Council of State Boards of Cosmetology Conference, summarized and reprinted in the National-Interstate Council of State Boards of Cosmetology Bulletin, December-January 2000, *available at* http://www.nictesting.org/Bulletins/NICBullDecJan00.pdf. If the bill

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6 H.R. 2100, Antitampering Act of 1999, 106th Session of Congress, 1st Session (1999).

7 To the extent that the industry claimed that the legislation was intended to protect consumer safety and welfare, it must be noted that under the Food, Drug and Cosmetic Act, it is already illegal to remove or alter batch or lot codes and expiration dates from infant formula and pharmaceuticals. 21 U.S.C. § 331(k).

had been passed, the BBSI would have "sent a message to our industry that unauthorized diversion can be stopped." *Id.* Many groups and associations mirrored the BBSI's efforts to eliminate secondary competition. Fortunately, their efforts were defeated and Congress did not deal a critical blow to the first sale doctrine by criminalizing removing product codes.

Although efforts to criminalize secondary competition wisely were defeated, aggressive use of the Lanham Act threatens to accomplish through litigation what industry forces could not do through legislative fiat, bar the secondary market from protecting itself by removing product identification codes. Manufacturers have sued retailers and secondary distributors under the Lanham Act, claiming that removing product codes violated the trademark and creates customer confusion.[8] While these suits have met with mixed results, with manufacturers winning in some courts and losing in other courts, the threat of Lanham Act litigation has had a chilling effect in the secondary markets, where distributors and retailers often operate on low margins. In short, misuse of the Lanham Act to stamp out secondary market competition threatens to eliminate the secondary market, harming both competition and consumers. This is inconsistent with the purpose of the Lanham Act and indeed runs counter to the procompetitive objectives of the intellectual property laws.

The Role of the Federal Trade Commission

The FTC has been at the forefront of enforcement to prevent the misuse of intellectual property protections to monopolize markets. In the pharmaceutical industry alone, FTC enforcement has resulted in several consent judgments and a landmark $100 million disgorgement order entered against Mylan Laboratories, Inc.[9] While the FTC's Hatch-Waxman[10] enforcement actions have garnered the most attention, the FTC has also

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8 *See, e.g., Bandag, Inc. v. Al Bolser's Tire Stores, Inc.*, 750 F.2d 903 (Fed. Cir. 1984); *John Paul Mitchell Systems v. Pete-N-Larry's, Inc.*, 862 F. Supp. 1020 (W.D.N.Y. 1994); *Davidoff & Cie, SA v. PLD Int'l. Corp.*, 263 F,3d 1297 (11th Cir. 2001) (all cases where the manufacturer prevailed on a Lanham Act theory), *but see Gramm Webb Int'l. v. Emporium Drug Mart*, 916 F. Supp. 909 (E.D. Ark. 1995); *John Paul Mitchell Systems v. Randalls Food Markets, Inc.*, 17 S.W.3d 721 (Tex. App. Austin 2000); *Sebastian Int'l., Inc. v. Longs Drug Store Corp.*, 53 F.3d 1073 (9th Cir. 1995) (all cases where the distributor or reseller prevailed on a Lanham Act theory).

9 *FTC v. Mylan Laboratories, Inc.*, CV 1:98CV03114 (TFH), Order Preliminarily Approving Proposed Settlements (Apr. 27, 2007); *see also, In re: Abbott Laboratories*, C-3945 (May 26, 2000); *In re: Hoechst Marion Roussel, Inc.*, Docket 9293 (March 16, 2000); *In re: Schering-Plough Corp.*, Docket 9297 (March 30, 2001).

10 Pub. L. N. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. § 355, 360cc, and 35 U.S.C. § 156, 271, 282.

considered other novel intellectual property practices that impact competition, including patent pooling, cross licensing and standard setting.

The Pharmaceutical Distributors Association submits that the use of federal intellectual property laws to inhibit and restrain vibrant secondary markets warrants a closer look by the FTC. Unlike the competitive effects of patent pooling and cross licensing, which at times may be difficult to discern, the effects of eliminating the secondary distribution market are clear, immediate and unambiguous. Without secondary distributors, consumers will face higher prices and fewer choices. On the other hand, there is no evidence that secondary distributors diminish the incentives to innovate, the primary goal of the intellectual property laws. Instead, the evidence suggests that manufacturers and designative distributors use the intellectual property laws to enforce vertical restraints and preserve supracompetitive profits.

The PDA encourages the FTC to investigate the aggressive use of intellectual property laws to inhibit secondary competition much in the same way it has investigated – and when appropriate brought enforcement actions in – other uses of intellectual property that run contrary to the federal antitrust laws. The PDA agrees with Chairman Muris' observation that properly understood and applied, both antitrust and intellectual property law should promote innovation and enhance consumer welfare. Unfortunately, as currently being used by creative manufacturers and their designated distributors, trademark law and other related intellectual property disciplines are being misused to the detriments of markets, competition and ultimately consumer welfare.

Sincerely,

Sal Ricciardi BP

SAL RICCIARDI
PRESIDENT
PHARMACEUTICAL DISTRIBUTORS ASSOCIATION